DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 29 1998 7374 '98 NOV -4 P1:45

Mr. Andrew M. Lessman
Chief Executive Officer
The Winning Combination
1125 Dawson Avenue
Henderson, Nevada 89015

Dear Mr. Lessman:

This is in response to your letter of October 16, 1998 to the Food and Drug Administration (FDA) responding to the agency's letter of September 9, 1998. FDA's September 9, 1998 letter to you was in response to your submission, dated August 31, 1998, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In our letter to your firm, we informed you that certain statements being made for the product "St. John's Emotional Lift" did not meet the requirements of 21 U.S.C. 343(r)(6) because they suggested that the products were intended to treat, prevent, or mitigate diseases, namely depression. A product that is represented to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases is subject to regulation under the drug provisions of the Act.

FDA has considered the information in your letter and is not persuaded that the statements that we identified in our previous letter to you are claims permitted pursuant to 21 U.S.C. 343(r)(6). As previously stated, if you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research.

A product that bears claims that represent it to diagnose, treat, cure, prevent or mitigate disease and that has not been approved by FDA is an unapproved new drug and is subject to regulatory action.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

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Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

THE WINNING™ COMBINATION
The Art and Science of Nutrition

Andrew M. Lessman
Chief Executive Officer

1125 Dawson Avenue
Henderson, Nevada 89015
702-564-9000 FAX 702-567-1005

October 16, 1998

60-98

RECEIVED
10/26/98

James T. Tanner, Ph.D
Division of Programs and Enforcement Policy
Food and Drug Administration
200 C Street SW
Washington, DC 20204

RE: St. John's Emotional Lift Label

Dear Dr. Tanner:

I received your letter on September 21st regarding our St. John's Emotional Lift product. The specific label copy upon which you commented was the result of very careful consideration to avoid customer confusion and any impression that this product is offered as an alternative to any care or treatment of any medical disease or condition. In addition to the standard disclaimer language that we insert on every product information panel regarding a product not being "*intended to diagnose, treat, cure or prevent any disease,*" the balance of the wording on the label was carefully chosen to be consistent with that language. Nevertheless, I appreciate the position stated in your letter about certain language on the label; however, I believe you will find the following discussion of the basis of that language persuasive.

Certainly, I have seen several St. John's products that make label claims that clearly fall outside the scope permitted by the relevant statutes and DSHEA. Consistent with my company's conservative positioning of product claims, and after familiarizing myself with the regulatory status of these types of products, we established the label copy for this product. The following is the specific language in question:

"... possess emotionally supportive properties in those individuals who are feeling mildly depressed."

If one looks at the language of the portion of the sentence in question, we never refer to the clinical condition or disease state of "depression" nor do we use the phrase "suffering from." Not only do we limit the descriptive to the past participle "depressed," but we also modify it to relate only to "feelings." Moreover, we further modify those "feelings" to being only "mild" in nature. Unlike other products, we at no time suggest this as an alternative therapy. Using the Oxford English Dictionary, the propriety of this sentence becomes clear. The first definition for "depressed" is to "make dispirited or sad." Certainly this meaning is neither severe nor connected to any disease condition. One must reach the fourth definition of "depressed" to see any connection with the word "depression," which is defined as "extreme melancholy, often with a reduction in vitality and physical symptoms." That is why we did not use the word "depression" and that is also why we further modified the word "depressed" with the word "mild" and connected it to the word "feeling." I inserted the additional modifying language to ensure total clarity. I wanted to be certain of avoiding customer confusion, which I presume to be FDA's goal as well, while also satisfactorily and fairly stating the product's properties. In showing this label to dozens of individuals, their perception of the label content is that this product is NOT intended for the treatment of depression. Clearly, the language that we have chosen to fairly describe this product, when combined with the FDA disclaimer language, can leave absolutely no doubt in any consumer's mind.

The language on this label is much the same as someone saying they "feel anxious," which in no way provides the impression that they are "suffering from an anxiety disorder." Similarly, when I say "I feel cold," it is quite different from saying "I have a cold" or "I am suffering from a cold." In closing, it is the words taken as a whole that define the meaning of the label. Accordingly, although the language on this label contains the word "depressed," which may cause an instant negative reaction by the FDA, when taken as a whole, it is a very conservative label. It does not direct itself toward the treatment of the disease of depression in any way. I trust that this correspondence serves to explain and support the label copy on the above-referenced product. I anxiously await your response.

Respectfully submitted,

Andrew M. Lessman
Chief Executive Officer
AML:skb